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Serial No.: 10/663,926

Confirmation No.: 2299

Filed: September 16, 2003

For: COMPOUNDS CONTAINING QUATERNARY CARBONS AND SILICON-CONTAINING GROUPS,
MEDICAL DEVICES, AND METHODS

Remarks

The Office Action mailed May 16, 2007 has been received and reviewed. Claims 1, 9, 10, 15, 17, 28, 29, 34, 40, 46, 47, 50, 55, 57, 66, and 76-77 having been amended, claims 71-75 having been previously cancelled without prejudice, the pending claims are claims 1-70 and 76-77. Reconsideration and withdrawal of the rejections are respectfully requested.

Double Patenting Rejection

Claims 1-70, 76, and 77 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,984,700. Claims 1-70, 76, and 77 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28, 30-34, 39, and 40 of copending Application No. 10/663,925. It is noted that copending Application No. 10/663,925 has not yet issued. Claims 1-70, 76, and 77 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-46 and 48 of copending Application No. 11/133,627. It is noted that copending Application No. 11/133,627 has not yet issued. Furthermore, each of these rejections is rendered moot in view of the amendments to the claims presented herein.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 1-70, 76, and 77 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that Applicants failed to define the term, "substantially free" as it pertains to ether, ester, and carbonate linkages. Although Applicants do not agree with the Examiner, this language has been amended solely in the interest of expediting prosecution. Thus, this rejection is rendered moot. Applicants reserve the right to pursue claims with such language and present appropriate arguments in a continuing application.

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MEDICAL DEVICES, AND METHODS**The 35 U.S.C. §112, Second Paragraph, Rejection**

The Examiner rejected claims 1-70, 76, and 77 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleged that in the absence of a definition of "substantially free," it cannot be determined what quantity of the ether, ester, and carbonate linkages may be present and still satisfy the claims. Although Applicants do not agree with the Examiner, this language has been amended solely in the interest of expediting prosecution. Thus, this rejection is rendered moot. Applicants reserve the right to pursue claims with such language and present appropriate arguments in a continuing application.

The Examiner rejected claim 77 under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps and elements, such omission amounting to gaps between the steps and elements. Although Applicants do not agree with the Examiner, claim 77 has been amended solely in the interest of expediting prosecution. Thus, this rejection is rendered moot. Applicants reserve the right to pursue claims with such language and present appropriate arguments in a continuing application.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 1-11, 14-16, and 40-49 under 35 U.S.C. §102(b) as being anticipated by Deichert et al. (U.S. Patent No. 4,208,506). This rejection is traversed; however, solely in the interest of expediting prosecution, each of independent claims 1 and 40 has been amended. Thus, this rejection is moot. Applicants reserve the right to pursue the previous claims and present appropriate arguments in a continuing application.

Applicants respectfully submit that claims 1-11, 14-16, and 40-49 are not anticipated by Deichert et al. because such document does not teach each and every aspect of the claimed invention. For example, Deichert et al. disclose "[m]onomeric polyparaffin siloxanes end-capped with activated unsaturated groups and polymers and copolymers thereof . . . for use as contact lenses and biomedical devices with improved properties" (e.g., abstract). However, Deichert et

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al. do not disclose a "*segmented* polymer comprising a *soft segment* comprising a group of the formula: $[-(R^1)_n-(Z-(R^2)_m)_p-(-Si(R)_2-V_r)_s-]_q-$ wherein ... *V is R'*" (e.g., independent claims 1 and 40, emphasis added).

As such, Applicants respectfully submit that claims 1-11, 14-16, and 40-49 are not anticipated by Deichert et al. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

The Examiner rejected claims 1, 2, 4, 6-16, 40, 41, 43, 45-51, and 53-56 under 35 U.S.C. §102(e) as being anticipated by Kato et al. (U.S. Patent No. 6,867,325). This rejection is traversed; however, solely in the interest of expediting prosecution, each of independent claims 1, 40, and 50 has been amended. Thus, this rejection is moot. Applicants reserve the right to pursue the previous claims and present appropriate arguments in a continuing application.

Applicants respectfully submit that claims 1-2, 4, 6-16, 40-41, 43, 45-51, and 53-56 are not anticipated by Kato et al. because such document does not teach each and every aspect of the claimed invention. For example, Kato et al. disclose an "organosiloxane polymer comprising recurring units of the general formula (1) and having a weight average molecular weight of 1,000-500,000" (e.g., abstract). However, Kato et al. do not disclose a *segmented* "polymer comprising a *soft segment* comprising a group of the formula:

$[-(R^1)_n-(Z-(R^2)_m)_p-(-Si(R)_2-V_r)_s-]_q-$ wherein ... *V is R'*" (e.g., independent claims 1, 40, and 50, emphasis added).

As such, Applicants respectfully submit that claims 1-2, 4, 6-16, 40-41, 43, 45-51, and 53-56 are not anticipated by Kato et al. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e).

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-70 and 76 under 35 U.S.C. §103(a) as being unpatentable over Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or WO

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98/54242, each in view of Pinchuk (U.S. Patent No. 6,197,240 or EP 821973). This rejection is traversed; however, solely in the interest of expediting prosecution, each of independent claims 1, 17, 40, 50, 57, and 76 has been amended. Thus, this rejection is moot. Applicants reserve the right to pursue the previous claims and present appropriate arguments in a continuing application.

The documents used as primary references (e.g., U.S. Patent No. 6,313,254, and PCT Patent Application Publication Nos. WO 01/07499, 00/64971, or 98/54242) disclose various silicon-containing polymers. However, there is no teaching or suggestion of a "segmented polymer comprising a *soft segment* comprising a group of the formula: $[-(R^1)_n-(Z-(R^2)_m-)_p-(Si(R)_2-V_r-)]_q$ wherein . . . *V* is *R'*. . . with the proviso that the polymer is free of carbonate linkages" (emphasis added).

Although Meijs et al. (U.S. Patent No. 6,313,254) disclose segmented polyurethanes, the soft segment is derived from "at least one polysiloxane macrodiol and at least one polyether and/or polycarbonate macrodiol" (e.g., Abstract, emphasis added).

Although WO 01/07499 generically describe polymers formed from diol compounds or diamine compounds, for example, in which R_7 can be a divalent linking group or hydrocarbon radical, all the examples that include silicon-containing segments are directed to siloxanes in which R_7 is oxygen. There is no enabling teaching, suggestion, or recognition of the advantages of the specific groups forming the soft segments of segmented polymers, as recited in Applicants' claims.

Although WO 00/64971 generically describe polymers formed from diol compounds or diamine compounds in which R_7 can be a divalent linking group or hydrocarbon radical, all the examples are directed to siloxanes in which R_7 is oxygen. There is no enabling teaching, suggestion, or recognition of the advantages of the specific groups forming the soft segments of segmented polymers, as recited in Applicants' claims.

Although WO 98/54242 generically describes polymers formed from diamine compounds or diol compounds in which R_7 can be a divalent linking group or hydrocarbon radical, all the examples are directed to carbonate-containing materials.

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Furthermore, the Examiner acknowledged that the "primary references fail to teach a specific preference for the incorporation of these quaternary carbon-containing groups within the silicon group-containing polyol or polyamine" (e.g., page 8, Final Office Action mailed 16 May 2007). In these documents there are no specific examples of segmented polymers that are free of carbonate linkages, wherein the soft segments include a group of the recited formula, in particular a quaternary carbon-containing group (one carbon with 4 other carbons attached), and no specific preference for the incorporation of these quaternary carbon-containing groups (although there are lists of species containing quaternary carbon-containing groups in certain of these documents). Furthermore, there is no enabling teaching, suggestion, or recognition of the advantages of the specific groups forming the soft segments of segmented polymers as recited in Applicants' claims.

Although Pinchuk '240 and Pinchuk '973 theoretically disclose that the "most inert polymers are those with the most 'quaternary' carbons" (e.g., col. 3, l. 62-64), the polyolefinic copolymer elastomers *do not contain silicon*. Although the Examiner stated that "Pinchuk discloses that polymers having increased amounts of quaternary carbons are the most 'medically' inert," there is no teaching or suggestion that this would also be true for polymers including silicon-containing moieties and quaternary carbons. Applicants submit that one of skill in the art would have no motivation to combine the silicon-containing polymers of the documents used as primary references with the non-silicon-containing polyolefinic copolymer elastomers of Pinchuk '240 and Pinchuk '973.

As such, Applicants respectfully submit that claims 1-70 and 76 are not obvious over Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or WO 98/54242, each in view of Pinchuk '240 (U.S. Patent No. 6,197,240) or Pinchuk '973 (European Patent Application Publication No. EP 821973). Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

The Examiner rejected claims 1-16 and 40-56 under 35 U.S.C. §103(a) as being unpatentable over Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or

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WO 98/54242, each in view of Pinchuk (U.S. Patent No. 6,197,240 or EP 821973) and further in view of Kennedy (U.S. Patent No. 4,316,973). This rejection is traversed; however, solely in the interest of expediting prosecution, each of independent claims 1, 17, 40, 50, 57, and 76 has been amended. Thus, this rejection is moot. Applicants reserve the right to pursue the previous claims and present appropriate arguments in a continuing application.

Although Kennedy teach the use of polyols that are rich in quaternary carbons to produce polyurethanes, the polyurethanes *do not contain silicon*. As such, Kennedy does not provide that which is missing from the combination of documents discussed above. Applicants submit that one of skill in the art would have no motivation to combine the silicon-containing polymers of the documents used as primary references with the non-silicon-containing polyolefinic copolymer elastomers of Pinchuk '240 and Pinchuk '973 and with the non-silicon-containing polyols of Kennedy.

Applicants respectfully submit that claims 1-16 and 40-56 are not obvious over Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or WO 98/54242, each in view of Pinchuk (U.S. Patent No. 6,197,240 or EP 821973) and further in view of Kennedy (U.S. Patent No. 4,316,973). Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

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MEDICAL DEVICES, AND METHODS**Summary**

It is respectfully submitted that the pending claims 1-70 and 76-77 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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August 16, 2007
DateBy: Ann M. Mueting
Ann M. Mueting
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Direct Dial (612) 305-1217**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 16th day of August, 2007, at 3:40pm (Central Time).

By: Sue Dombroske
Name: Sue Dombroske